UNITED STATES DISTRICT COURT DISTRICT OF MAINE

BTL INDUSTRIES INC.,)	
)	
Plaintiff)	
)	
v.)	No. 1:23-cv-00032-SDN
)	
REJUVA FRESH LLC and)	
POLLY JACOBS)	
)	
Defendants)	

RECOMMENDED DECISION ON CLAIM CONSTRUCTION

In this consolidated action, BTL Industries Inc. alleges that Rejuva Fresh LLC and Polly Jacobs, Rejuva Fresh's sole owner and shareholder, (collectively, "Rejuva Fresh") manufacture and sell noninvasive body-contouring devices that infringe the following BTL patents: United States Patent Nos. 11,266,852 ('852 Patent) (ECF No. 57-1), 10,695,575 ('575 Patent) (ECF No. 57-2), 10,478,634 ('634 Patent) (ECF No. 57-3), 9.636,519 ('519 Patent) (ECF No. 57-4), 10.596,386 ('386 Patent) (ECF No. 57-5), 11,679,255 (255)No. and Patent) (ECF 129-6). See generally Second Amended Complaint (ECF No. 93); BTL v. Rejuva Fresh, 1 23, No. 1:24-cv-00139-SDN, ECF No. (D. Me. Apr. 2024) [hereinafter "24cv139 Complaint"]. This matter is before me on the issue of claim construction. After reviewing the record, and considering the parties' evidence and argument, I recommend the Court construe the disputed claim terms as follows.

I. Background

BTL develops and sells noninvasive body-contouring devices and recently

launched a new series of devices featuring its "proprietary technology that uses high-intensity electromagnetic stimulation to tone and strengthen muscles in targeted areas." ECF No. 93 ¶ 12. Rejuva Fresh has begun competing against BTL "by manufacturing and selling non-invasive body-contouring devices, which utilize electromagnetic waves to generate muscle contractions." *Id.* ¶ 28. In response, BTL brings the following claims against Rejuva Fresh: patent and trademark infringement, unfair competition, false designation of origin, false advertising, and violation of the Maine Uniform Deceptive Trade Practices Act. *See id.* ¶¶ 55-171; *see also* 24cv139 Complaint ¶¶ 37-83.

BTL alleges that the devices Rejuva Fresh manufactures and sells infringe the patents and trademarks associated with the proprietary technology featured in two of its products: (1) the EMSCULPT body-contouring device, which generates "high-intensity electromagnetic energy" that "induce[s] powerful muscle contractions in a patient" to noninvasively tone and sculpt their body; and (2) the EMFACE facial-contouring device, which "applies a combination of synchronized radiofrequency [that] heats the dermis to stimulate collagen and elastin production" and "high-intensity facial electromagnetic stimulation" that "selectively contracts facial muscles" to noninvasively tone a patient's muscles and sculpt their face. See ECF No. 93 ¶¶ 2, 12-14, 20-54; 24cv139 Complaint ¶¶ 3, 13-15, 20-36. Rejuva Fresh denies that its products infringe BTL's intellectual property. See generally Amended Complaint (ECF Answer No. 122); to Supplemental Amended Answer to Amended Complaint (ECF No. 123).

II. Legal Standard

"The grant of a patent is the grant of a monopoly, in exchange for which . . . the inventor is required to teach to others skilled in the art, in clear and precise language, how to practice the patented invention." *Marical, Inc. v. Cooke Aquaculture Inc.*, No. 1:14-cv-00366-JDL, 2016 WL 3676152, at *2 (D. Me. July 6, 2016) (rec. dec.) (citations omitted), *aff'd in part*, 2016 WL 4579074 (D. Me. Sep. 2, 2016). This "definiteness requirement" both "ensures that those skilled in the art will be able to practice the invention" and "provides notice of the scope of the patent." *Id.*

Consequently, every patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention." 35 U.S.C. § 112(b). For those claims to be definite, their terms "must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 909 (2014) (cleaned up). The definiteness requirement strikes a "delicate balance" between accepting "[s]ome modicum of uncertainty"—given "the inherent limitations of language"—as the price of incentivizing innovation, while guarding against patent applicants "injecting ambiguity into their claims" to generate "a zone of uncertainty" about the scope of their invention "which enterprise and experimentation may enter only at the risk of infringement claims." *Id.* at 909-10 (cleaned up).

In light of these "competing concerns," the Supreme Court has interpreted section 112 of the Patent Act "to require that a patent's claims, viewed in the light of

the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Id.* at 910. Although patents and the claims therein are presumed valid, they may be rendered invalid if they fall short of the definiteness requirement. *See* 35 U.S.C. §§ 112(a)-(b), 282(a), (b)(3)(A).

The first phase of a patent infringement action—and the current stage of this litigation—involves construing "the language used in the patent to describe the claimed invention." *Marical, Inc.*, 2016 WL 3676152, at *2 (citation omitted). Claim construction is a matter of law, "though the construction of a claim term can have evidentiary underpinnings that require subsidiary factfinding." *Id.* (cleaned up).

"A claim term is construed according to its ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of invention." Wavetronix LLC v. EIS Elec. Integrated Sys., 573 F.3d 1343, 1355 (Fed. Cir. 2009) (citation omitted). Therefore, when construing a claim term, the court looks first to the publicly available sources "that show what a person of skill in the art would have understood disputed claim language to mean," including "the words of the claims themselves, the remainder of the specification, [and] the prosecution history." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (cleaned up). "The prosecution history... consists of the complete record of the proceedings before the [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." Id. at 1317 (citation omitted). Moreover, though "it is less significant than the intrinsic record in determining the legally operative meaning of claim language," the court may also examine extrinsic evidence, such as

treatises, dictionaries, and expert testimony. *Id.* at 1317-18 (cleaned up).

III. Person of Ordinary Skill in the Art

As a preliminary matter, the parties dispute how to define a person of ordinary skill in the art (POSITA) at the time of the alleged invention of the claimed devices.

BTL argues that a POSITA is someone "familiar with the design, development, and use of devices that apply radiofrequency energy and/or pulsed electrical energy to the body to stimulate biological tissue" ECF No. 130 at 4. This includes (1) "a person with at least a bachelor's degree in electrical engineering, biomedical engineering, physics, or a related field of study, and at least two years' experience in academia or industry researching, designing, or developing such devices," and (2) "a medical doctor, healthcare professional, researcher, or other person [with] a degree in medicine, physiology, neuroscience, kinesiology, physical therapy, biomechanics, or a related discipline and two or more years of using, researching, designing, or developing such devices." *Id.* at 4-5; *see* ECF No. 58 at 5.

Rejuva Fresh agrees that a POSITA should be someone familiar with the "use of devices that apply radiofrequency energy and/or pulsed electrical energy," see ECF No. 137 at 4, but contends this definition should be limited to "an operator or technician with the knowledge or training necessary to operate the claimed devices," id., such as "a two year associate['s] degree or higher, and/or . . . a certificate of training in [their] use," ECF No. 71 at 4.

Determining the characteristics of a POSITA is a question of fact. See ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010).

The following non-exhaustive list of factors guides this analysis: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." Best Med. Int'l., Inc. v. Elekta Inc., 46 F.4th 1346, 1353 (Fed. Cir. 2022) (cleaned up).

Neither party explains how these factors inform their proposed POSITA definitions. My analysis is therefore guided by the record and relevant authorities.

Rejuva Fresh's proposed definition—which limits a POSITA to those capable of operating the claimed devices—is simply too narrow. In the context of defining a POSITA, the relevant "art" is that "which one can reasonably be expected to look [to] for a solution to the problem that a patented device tries to solve." Biogen Int'l GmbH v. Mylan Pharms. Inc., No. 1:17CV116, 2020 WL 3317105, at *7 (N.D. W. Va. June 18, 2020) (cleaned up). This inherently includes more than the claimed devices; indeed, a POSITA is presumed to be familiar with prior relevant art. See Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 449 F. Supp. 3d 967, 991 (D. Nev. 2020) (stating that a POSITA "is a hypothetical person who is presumed to have access to, and be aware of, all of the relevant prior art at the time of invention"). Importantly, a POSITA is someone capable of making—not simply using—the full scope of the inventions as taught by the patents-in-suit. See 35 U.S.C. 112(a).

In contrast, the experience and education set forth in BTL's proposed POSITA definition is consistent with relevant case law given the claimed devices' sophistication and the technological problems in the art they are intended to solve.

The patents-in-suit purport to improve upon prior art approaches to noninvasive aesthetic body treatments; for example, they describe how prior art consisted of manually controlled devices that inefficiently delivered single-energy results. treatments. produced non-homogenous generated side effects (e.g., panniculitis and pain or burns), did not enhance the visual appearance of muscle, and, in the case of the '255 Patent, were unadaptable to rugged, uneven treatment areas like the face. See '575 Patent at 1:53-4:61; '255 Patent at 1:18-4:9; '852 Patent at 1:20-4:24; '386 Patent at 1:14-3:3; '519 Patent at 1:7-2:33; '634 Patent at 1:53-4:61. The inventions claimed purport to solve these problems by enabling unattended treatment by way of physically adaptable applicators and delivering an efficient combination of electromagnetic energy and an auxiliary energy that reduces treatment duration, results in more significant and homogenous remodeling of the targeted tissue, and reduces or eliminates attendant safety risks and side effects. See '575 Patent at 1:53-4:61; '255 Patent at 1:18-4:9; '852 Patent at 1:20-4:24; '386 Patent at 1:14-3:3; '519 Patent at 1:7-2:33; '634 Patent at 1:53-4:61.

Moreover, in cases involving similarly sophisticated patents, courts have defined a POSITA to include those educated and experienced in both the technical and clinical aspects of the relevant art. *See, e.g., OrthoPediatrics Corp. v. Wishbone Med., Inc.*, No. 3:20-CV-929 JD, 2022 WL 4978169, at *3-4 (N.D. Ind. Oct. 4, 2022) (finding, in a patent infringement case involving computer systems for interpreting medical images and medical treatments for orthopedic issues, that a POSITA was "a person with (1) at least a bachelor's degree or equivalent degree and (2) at least two

years of experience in (i) designing, developing or testing computer systems used in medical applications for interpreting medical images, or (ii) using computer systems for medical treatments, including but not limited to orthopedic alignment, or a person having equivalent knowledge and experience in the field of orthopedic alignment"); Nevro Corp. v. Stimwave Techs., Inc., No. 19-325-CFC, 2019 WL 3322368, at *9 n.5 (D. Del. July 24, 2019) (accepting the parties' agreement, in a patent infringement case involving spinal cord stimulation devices, "that a POSITA would have several years of experience developing active implantable medical devices, either from a technical or clinical side, and would have an educational background in some relevant field, whether it's medicine, engineering, software development, [or] something that would be used to develop the product" (cleaned up)).

I therefore recommend, based on the record and relevant authorities, that the Court find a POSITA at the time of the inventions claimed in the patents-in-suit would have the range of education and experience proposed by BTL.

IV. Claim Construction

A. "Enhance the visual appearance of the patient" and "toned"

The parties dispute whether the descriptive terms "enhance the visual appearance of the patient" and "toned" are indefinite under 35 U.S.C. § 112. See ECF No. 54 at 14-15. As described above, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, 572 U.S. at 901. Although "descriptive

words (or terms of degree) in a claim may inherently result in broader claim scope than a claim defined with mathematical precision," they are rendered indefinite only "where the intrinsic evidence (or extrinsic evidence, where relevant and available) provides insufficient guidance as to any objective boundaries for the claims—including where the claims are 'purely subjective' such that their scope cannot be determined with reasonable certainty." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1347-48 (Fed. Cir. 2022) (cleaned up). Rejuva Fresh bears the burden of proving indefiniteness by clear and convincing evidence. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

The term "enhance the visual appearance of the patient" is employed in the '852 Patent, while "toned" appears in the '575 and '386 Patents, as exemplified below:

[W]herein the first and the second magnetic field generating coils are configured to be placed proximate to a body region of the patient such that the first and second time-varying magnetic fields are each applied to the body region to cause a contraction of at least one muscle in the body region to enhance the visual appearance of the patient

Claim 9, '852 Patent, 114:22-28 (emphasis added).

[W]herein the belt is configured to aid in positioning the applicator in order to apply the time-varying magnetic field with at least motor-threshold magnetic flux density to a peripheral neural system innervating the [sic] at least one muscle of the patient in order to repetitively contract the [sic] at least one muscle within the body region such that the [sic] at least one muscle is *toned*....

Claim 12, '386 Patent at 29:26-32 (emphasis added).

A method for toning muscles of a patient, comprising: . . . applying a first plurality of impulses generated by the first magnetic field generating coil and applying a second plurality of impulses generated by the second magnetic field generating coil, to muscle fibers, neuromuscular plates, or nerves innervating muscle fibers in a body region of the patient to

cause muscles of the body region to contract such that the muscles are *toned*.

Claim 1, '575 Patent at 107:49-108:22 (emphasis added).

Rejuva Fresh argues that the two terms are "purely subjective" because their intrinsic evidence lacks any objective baseline with which a POSITA might reasonably determine their bounds. ECF No. 57 at 15-21. BTL counters that the objective baseline "is that a magnetic field is applied to cause a contraction of the muscle," and regardless of the disputed terms' facial subjectivity, ECF No. 58 at 17, a "POSITA reading the claims (and specification) as a whole would be aware that the recited magnetic fields will cause muscular contraction, which will create the 'toned' and 'enhanced visual appearance' recited," ECF No. 70 at 9.1

As Rejuva Fresh points out, however, the question is not whether a "toned" or "enhanced visual appearance" is linked to muscular contractions induced by magnetic fields, but whether those terms are sufficiently defined such that a POSITA is equipped with objective standards that both enable practice of the invention and provide notice of its scope, see ECF No. 71 at 11; Marical, 2016 WL 3676152, at *2; see also Enzo Biochem, Inc. v. Applera Corp., 599 F.3d 1325, 1332 (Fed. Cir. 2010) ("When a word of degree is used, the court must determine whether the patent provides some standard for measuring that degree." (cleaned up)).

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¹ As Rejuva Fresh correctly notes, *see* ECF No. 71 at 6-8, BTL's proffered extrinsic evidence does not aid my analysis because it was either (1) generated after the '852, '575, and '386 Patents' filing dates, and therefore cannot inform my inquiry, *see Phillips*, 415 F.3d at 1313 (explaining claim terms are construed based on what they meant to a POSITA "at the time of the invention, i.e., as of the effective filing date of the patent application"), or (2) unpersuasive because, like the majority of BTL's briefing on this point, it provides extensive information about how the claimed technology functions but fails to offer any objective boundaries by which a POSITA might measure the disputed terms of degree.

Because the '852, '575, and '386 Patents do not specifically define "toned" or "enhance the visual appearance of the patient," cf. Nevro Corp. v. Boston Scientific Corp., 955 F.3d 35, 39 (Fed. Cir. 2020) (noting the meaning of "paresthesia" was specifically defined and undisputed), BTL references phrases in the patents' specifications that it maintains resolve any uncertainty about the meaning of the allegedly indefinite terms.² For example, the '852 Patent discloses that prior art was "not able to provide enhanced visual appearance of a muscle, e.g. muscle shaping, toning and/or volumization effect," '852 Patent at 1:60-62, and that the claimed "treatment may enhance the visual appearance of scars and/or stretchmarks by providing improved the [sic] growth of collagen and/or elastin fibers to provide the skin younger, firmer, and/or smoother appearance," id. at 73:56-60, enhance the visual appearance of a patient's breasts by firming or elevating breast tissue, see id. at 108:27-39, or generally enhance the visual appearance of a patient by toning and/or strengthening muscles to create a body shaping effect, see id. at 72:59-61. Similarly, the '575 and '386 Patents disclose that "treated muscles may be strengthened, toned, the cellulite may be reduced and dimples may be removed," '575 Patent at 30:62-64, "[t]he buttock may become firm, toned and/or round shaped," id. at 39:54-55, and that muscle contractions induced by magnetic fields "may help to tone the muscle providing a more attractive appearance," '386 Patent at 13:48-50.

I agree with Rejuva Fresh that nowhere in this "litany of mays" is there an objective definition identifying a standard for determining when a patient is "toned"

² The parties do not contend the patents' prosecution histories affect this indefiniteness analysis.

or their visual appearance is "enhanced"; indeed, the bulk of the disclosures BTL references lean on similar terms of degree. Int'l Test Sols., Inc. v. Mipox Int'l Corp., No. 16-cv-00791-RS, 2017 WL 1367975, at *5 (N.D. Cal. Apr. 10, 2017) (cleaned up); see ECF No. 71 at 8-9, 11; see also Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1373 (Fed. Cir. 2014) (declining "to cull out a single 'e.g.' phrase from a lengthy written description to serve as the exclusive definition of a facially subjective claim term"). While these disclosures might improve a POSITA's overall understanding of the invention's purpose or function, they offer no objective guideposts for delineating claim scope. See In re Walter, 698 F. App'x 1022, 1026 (Fed. Cir. 2017) ("If a claim employs a term of degree, the intrinsic record must provide those skilled in the art with 'objective boundaries' with which to assess the term's scope. If it does not, the claim is indefinite." (cleaned up)). Cf. Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1349 (Fed. Cir. 2005) (concluding that intrinsic evidence which provided helpful context but no definition of the phrase "aesthetically pleasing" was insufficient to defeat indefiniteness because "[m]erely understanding" the claimed interface screen's "aggregate layout of elements" or "look and feel" did nothing to help a POSITA ascertain whether a given interface screen was "aesthetically pleasing").

Moreover, the disputed terms purportedly cover a range of physical effects that make a patient look sufficiently "toned" or "enhance the[ir] visual appearance" and exclude those that do not, but the relevant patents' intrinsic records offer no frame of reference—such as comparative examples or studies—to aid a POSITA in determining whether a given device creates a result that falls into those categories.

See ECF No. 71 at 9, 11; In re Walter, 698 F. App'x at 1026; see also Datamize, 417 F.3d at 1350 ("In the absence of a workable objective standard, [a term of degree] does not just include a subjective element, it is completely dependent on a person's subjective opinion."). Cf. Sonix Tech. Co., Ltd. v. Publ'ns Int'l, Ltd., 844 F.3d 1370, 1378-79 (Fed. Cir. 2017) (concluding "visually negligible" was definite where the patent provided an objective baseline of "negligible to human eyes" as well as exemplary designs for and examples of visually negligible indicators); Nevro, 955 F.3d at 39-40 (concluding "paresthesia-free" was definite where the patent defined the term, provided "detailed guidance and examples of systems and devices that generate and deliver paresthesia-free signals" using certain parameters, and included a study comparing the claimed signals' effects against conventional ones).

For these reasons, I conclude that Rejuva Fresh has met its burden of establishing, by clear and convincing evidence, that the terms "toned" and "enhance the visual appearance of the patient" are indefinite. See 35 U.S.C. § 112(a)-(b).

B. "Configured to"

BTL proposes that the undefined term "configured to" should be construed to mean "designed to," see ECF No. 58 at 6-8, while Rejuva Fresh counters that the term's proper construction is "set up to," see ECF No. 57 at 9-14. The parties' disagreement largely centers on whether the patents-in-suit teach that the device is already designed to function as claimed, see, e.g., Aspex Eyewear, Inc. v. Marchon Eyewear, Inc., 672 F.3d 1335, 1348-49 (Fed. Cir. 2012), or that it must be set up by an operator to perform those specific functions, see, e.g., Nevro, 955 F.3d at 40-42.

The disputed term appears in the '386 Patent, the '852 Patent, and the '255 Patent, as exemplified in part below:

[A]n applicator *configured to* be held in contact with a body region of the patient with a belt, . . . wherein the belt is *configured to* aid in positioning the applicator

Claim 12, '386 Patent at 29:12-27 (emphasis added).

[W]herein the first magnetic field generating coil is *configured to* generate a first time-varying magnetic field with a repetition rate in a range of 1 Hz to 300 Hz and a magnetic flux density in a range of 0.1 Tesla to 7 Tesla

Claim 9, '852 Patent at 113:59-63 (emphasis added).

[W]herein the user interface is *configured to* allow a selection of the preprogrammed treatment protocol, wherein the treatment protocol comprises a set of parameters of the radiofrequency energy and the pulsed electric current

Claim 13, '255 Patent at 32:4-8 (emphasis added). The parties confirmed at oral argument on May 13, 2025, that the disputed term "configured to" should be construed consistently across the '852, '255, and '386 Patents.

In Aspex, the Federal Circuit construed the following claim: "said arms and said pair of magnetic members adapted to extend across respective side portions of a primary spectacle frame." Aspex, 672 F.3d at 1348. In the context of that language, the court concluded "the phrase 'adapted to' [was] most naturally understood to mean that the arms and magnetic members [were] designed or configured to accomplish the specific objective, not simply that they [could] be made to serve that purpose." Id. at 1349. The court noted "adapted to' is frequently used to mean 'made to,' 'designed to,' or 'configured to,'" and "can also be used in a broader sense to mean

'capable of' or 'suitable for," but affirmed the trial court's narrower "configured to" construction for two reasons: (1) the specifications described "the magnetic members of the auxiliary frame as being 'for engaging' with the magnetic members of the primary frame," suggesting the former were "meant to engage with" the latter, "not simply that they [were] capable of doing so"; and (2) an adjacent claim used the phrase "capable of engaging" in a parallel setting, indicating "adapted to' was intended to have a different meaning from 'capable of." *Id.* at 1349 (citations omitted).

In contrast, the Federal Circuit in *Nevro* concluded the phrase "configured to" meant "programmed to" instead of "designed to" where the claim language and specifications of patents pertaining to high-frequency spinal cord stimulation therapy expressly contemplated that "configured to' require[d] programming the signal generator (i.e., setting parameters) to generate the claimed signals." *Nevro Corp.*, 955 F.3d at 37, 41 (noting claim language reciting a "signal generator configured to generate... wherein at least a portion of the therapy signal is at a frequency signal of 10 kHz, and at a current amplitude range from 0.1 mA to 20 mA," and "a step for configuring the signal generator, including programming," as well as specification language confirming that "configured to' require[d] setting parameters"). The court also noted this construction tracked with the prosecution history, where Nevro "consistently distinguished the claimed invention from the prior art on the basis that the prior art did not disclose specific parameters for a signal generator." *Id.* at 41.

Unlike in *Nevro*, the claim language of the relevant patents-in-suit does not indicate that "configured to" involves or requires action by an operator. Claim 18 of

the '386 Patent, for example, uses the phrase "configured to" when describing how certain device components function, see '386 Patent at 30:33-35, while Claim 20 of the same patent specifically describes a patient's treatment parameters as "set" by an operator, see id. at 30:54-57. "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims." Comark Comme'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998). Indeed, a better reading of the relevant claim language tracks the reasoning in Aspex and supports construing "configured to" to mean the coil was "designed to" deliver a range of energy, the user interface was "designed to" allow the selection of preprogrammed treatments, and the applicator and belt were "designed to" function in tandem to effectuate treatment, regardless of the operator's ultimate use of the device. As the Court put it in its most recent order in this case, the use of "configured to" throughout the '852 Patent's claim language "suggests the device was designed (in the past) to achieve the claimed function, not that it may be set up (in the future) to do so." Order on Motion for Preliminary Injunction and Motion to Strike (ECF No. 163) at 12.

The specifications of the relevant patents-in-suit support this construction. "Configured to" and "set up" both appear in the '255 and '852 Patents' specifications, reinforcing the presumption that their meanings were intended to differ. *Compare* '255 Patent at 29:43-46 (noting the method of treatment may include "preparation of the tissue; positioning the proposed device; selecting or setting up the treatment parameters; and application of the energy"), *with id.* at 24:40-44 ("The control unit (CPU) is configured to provide a treatment protocol energizing by

alternating electric currents only those electrodes located in proximity or above the anatomical area 1 and 2"), and compare '852 Patent at 25:62-64 ("A magnetic flux density may be set up as [the] highest magnetic flux density value acceptable by the patient."), with id. at 3:63-65 ("Present method and devices may also include sensors configured to measure various parameters of the scanning unit").

Rejuva Fresh argues finally that the '386 Patent's prosecution history supports the conclusion that an operator must "set up" the treatment parameters for the device to function as claimed because the patentee in this case, like in *Nevro*, distinguished the invention from prior art based on the claimed treatment parameters.³ See ECF No. 74 at 5. Both the '386 Patent's specification and prosecution history note that prior art employed lower ranges of magnetic flux density or repetition rates, while the new invention enables more effective treatment by using higher ranges. See ECF No. 74-1 at 12, 16, 19; '386 Patent at 1:64-3:3. I am unpersuaded, however, that this evidence is sufficient to demonstrate that the device requires operator intervention and is not already "designed to" function within the claimed range, particularly where the term "configured to" is frequently used in contexts unrelated to treatment parameters through the relevant patents-in-suit and "can be defined whole." only that comports with the instrument Westview Instruments, Markman υ. *Inc.*, 517 U.S. 370, 389 (1996);see, e.g., '386 Patent at 29:12-13; '255 Patent at 33:7-8; '852 Patent at 116:27-29.

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³ The parties' only other arguments concerning the relevant patents' prosecution histories were entirely perfunctory and will therefore be treated as waived. *See*, *e.g.*, ECF No. 57 at 12; ECF No. 70 at 5; *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990).

Accordingly, I conclude that a POSITA, after consulting the '852, '255, and '386 Patents' claim language, specifications, and prosecution histories, would understand the plain and ordinary meaning of "configured to" to be "designed to." Because the intrinsic evidence is sufficient to resolve this dispute, I need not consider the parties' proffered extrinsic evidence. See Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 832 (Fed. Cir. 2003) ("Resort to extrinsic evidence is appropriate only when an ambiguity remains after consulting the intrinsic evidence of record.").

C. "Arranged on a circumference of"

The parties agree that the term "arranged on a circumference of" should be construed according to its plain and ordinary meaning as understood by a POSITA at the time of the claimed invention, but their proposed constructions diverge. See ECF No. 54 at 15. BTL contends that the term's plain and ordinary meaning is "the blower is arranged in close proximity with the circumference of the coil," while Rejuva Fresh proposes that it means "the blower is arranged in contact with the circumference" of the coil. Id. (emphasis added). The disputed term is not specifically defined but it appears, for example, in Claim 1 of the '519 Patent:

A magnetic stimulation device producing a time varying magnetic field for treatment, comprising: a connection to an energy source, a switch, a coil, an energy storage device, at least one blower and a casing; with the blower *arranged on a circumference of* the coil; and wherein the coil and the casing are arranged in a manner that fluid can flow in-between them and wherein the coil is cooled by fluid flow over at least upper and lower sides of the coil.

Claim 1, '519 Patent at 6:21-30 (emphasis added). The plain language of Claim 1 offers no clear indication of how "arranged on a circumference of" should be construed;

accordingly, I turn to the '519 Patent's specification and prosecution history.

Figure 2 of the '519 Patent illustrates a cross-section of the magnetic applicator that depicts the coil (10), circuit wires (11), fastening points (12), blower (13), applicator (14), and arrows indicating fluid flow (15). *See id.* at 4:4-39, Fig. 2.

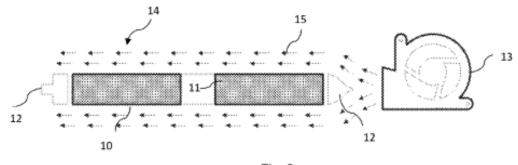


Fig. 2

The '519 Patent's specification discloses that the fastening points both connect and keep the coil and the applicator casing (not depicted in Figure 2) "spaced apart so that fluid (which may be air or any liquid) can flow between them." *Id.* at 4:15-19. The blower, which directs that fluid from within the casing, *see id.* at 2:5-6, can be arranged "around the circumference of the coil, or perpendicular to the coil," to "allow[] air to bypass the coil from upper and lower (patient's) sides," *id.* at 4:19-24 (emphasis added). As BTL notes, Figure 2 reflects this embodiment by spacing the blower apart from, instead of against, the coil. *See* ECF No. 73 at 3.

Rejuva Fresh argues that "around the circumference," see '519 Patent at 4:20, is a different embodiment than "on a circumference," see id. at 6:25, and it would be improper to conflate the two, see ECF No. 57 at 22-23 (citing CAE Screenplates Inc v. Heinrich Fiedler GmbH, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("[W]e must presume that the use of these different terms in the claims connotes

different meanings.")). Unlike in *CAE Screenplates*, however, only the latter phrase appears in the claim language. Moreover, it is the specification, not the claim language, that sets forth embodiments. *See Phillips*, 415 F.3d at 1323 (describing the purposes of a patent's specification and its relationship to the claim language).

I am also unpersuaded that the patentee's use of the word "on" to describe how other device components are physically connected supports construing "arranged on a circumference of" to mean that the blower is in contact with the coil. See ECF No. 57 at 21-22; see also Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 991 (Fed. Cir. 1999) ("Varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition."). Claim terms "can be defined only in a way that comports with the instrument as a whole," Markman, 517 U.S. at 389; correspondingly, "an interpretation which excludes a disclosed embodiment from the scope of the claim is rarely, if ever, correct," Broadcom Corp. v. Emulex Corp., 732 F.3d 1325, 1333 (Fed. Cir. 2013) (cleaned up). Adopting Rejuva Fresh's proposed construction would improperly exclude the embodiment in Figure 2. See Oatey Co. v. IPS Corp., 514 F.3d 1271, 1277-78 (Fed. Cir. 2008) (rejecting the construction of a claim that excluded an embodiment disclosed in a figure).

The '519 Patent's prosecution history sheds no light on the proper construction. In its response to a Patent and Trademark Office Action, the patentee clarified that the blower cools the coil by directing fluid over its upper and lower sides, using the term "arranged on a circumference" to describe the blower's position

relative to the coil, in an ultimately successful attempt to distinguish the '519 Patent from prior art. See ECF No. 60-16 at 85-91. Nothing in the patentee's response indicates whether they intended the blower to be spaced apart from or in contact with the coil. Further, contrary to Rejuva Fresh's argument, the patentee did not disavow claim scope beyond the blower being in contact with the coil by describing their relative positions using the word "on" instead of "around." See ECF No. 57 at 24. The patentee distinguished the '519 Patent from prior art by explaining that the prior art was either "silent about [the] use or arrangement of a blower for cooling a coil" or used the blower to direct airflow around the coil differently. ECF No. 60-16 at 88-90. This falls far short of a "clear and unmistakable" prosecution disclaimer. Genuine Enabling Tech. LLC v. Nintendo Co., Ltd., 29 F.4th 1365, 1374 (Fed. Cir. 2022).

Viewing the '519 Patent's intrinsic evidence as a whole, the specification clearly favor of tilts the scales in BTL's proposed construction. See Phillips, 415 F.3d at 1316-17 (emphasizing it is "entirely appropriate for a court ... to rely heavily" on the specification for guidance when construing claims because the Patent and Trademark Office "determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art" (cleaned up)). I therefore conclude that the term "arranged on a circumference of" reasonably means the blower is "arranged in close proximity with the circumference of" the coil. This definition constitutes the plain and ordinary construction of the term as it would be understood by a POSITA after consulting the '519 Patent's intrinsic evidence.

D. "An electrode"

The parties dispute the meaning of the term "an electrode." While BTL contends the term should be construed plainly to mean "one or more electrodes," and that later references to "the electrode" reflect the same potential plurality, Rejuva Fresh proposes that the term should be construed to mean "one or more electrodes, at least one of which is configured to apply radiofrequency energy and configured to apply pulsed electric current." ECF No. 154 at 3-4. The disputed term appears in the '255 Patent, as illustrated in pertinent part below:

A device for a treatment of a patient, comprising: a pad comprising *an electrode*, wherein the pad and *the electrode* are configured to be attached to a body part of a patient during a treatment . . .

wherein *the electrode* is configured to apply radiofrequency energy in a range of 400 kHz to 80 MHz to the body part of the patient, . . .

wherein *the electrode* is configured to apply a pulsed electric current with a duration in a range of 0.1 µs to 10 s to the body part, . . . and

wherein *the electrode* is configured to provide the radiofrequency heating and the electric muscle stimulation during the treatment

Claim 1, '255 Patent at 30:51-67 (emphasis added).

A device for treating a patient by radiofrequency energy and a pulsed electric current, the device comprising: . . . *an electrode* coupled to the underside of the flexible substrate; and an adhesive coupled to the underside of the flexible substrate and to *the electrode*,

... wherein *the electrode* is configured to apply *radiofrequency energy* to the body part to cause heating of the body part, and . . .

wherein *the electrode* is configured to apply *pulsed electric current* to the body part to cause a muscle contraction of a muscle

Claim 16, *id*. at 32:23-40 (emphasis added).

The Federal Circuit "has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising." KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000). "The subsequent use of definite articles 'the' or 'said' in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning." Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1342 (Fed. Cir. 2008); see also Lite-Netics, LLC v. Nu Tsai Capital LLC, 60 F.4th 1335, 1346 (Fed. Cir. 2023) (concluding that the use of "the' or 'said' when referring back to an antecedent 'a' phrase . . . does not itself suffice to demand the singular meaning because if the 'a' phrase means 'one or more,' so would the subsequent reference-back phrases"). Indeed, "exceptions to this rule are extremely limited" and "only arise where the language of the claims themselves, the specification, or the prosecution history necessitate [such] a departure." Baldwin, 512 F.3d at 1342-43 (emphasizing that "a patentee must evince a clear intent to limit 'a' or 'an' to 'one" (cleaned up)).

In this case, the parties agree that the phrase "an electrode" means "one or more electrodes," ECF No. 154 at 3-4, but they dispute the functionality the '255 Patent's claims require of those electrodes. Rejuva Fresh contends that the plain language of the claims requires at least one electrode to be capable of delivering both radiofrequency energy and electric current, see ECF No. 155 at 5, while BTL asserts that the claim language also permits (and the specification supports) the use of

distinct electrodes to deliver the two energies separately, see ECF No. 164 at 5.

The Federal Circuit's opinion in Salazar v. AT&T Mobility LLC is instructive.
64 F.4th 1311, 1315-17 (Fed. Cir. 2023). In that case, the court affirmed the district court's construction of "a microprocessor" in the context of the following claim:

A communications, command, control and sensing system for communicating with a plurality of external devices comprising:

a microprocessor for generating a plurality of control signals used to operate said system, said microprocessor <u>creating</u> a plurality of reprogrammable communication protocols, for transmission to said external devices wherein each communication protocol includes a command code set that defines the signals that are employed to communicate with each one of said external devices;

a memory device <u>coupled to</u> said microprocessor configured to store a plurality of <u>parameter sets retrieved</u> by said microprocessor so as to recreate a desired command code set, such that the memory space required to store said parameters is smaller than the memory space required to store said command code sets;

a user interface <u>coupled to</u> said microprocessor for <u>sending</u> a plurality of signals corresponding to user selections to said microprocessor and displaying a plurality of menu selections available for the user's choice, <u>said microprocessor generating</u> a communication protocol in response to said user selections; and

an *infra-red* frequency transceiver <u>coupled</u> to said microprocessor for transmitting to said external devices and receiving from said external devices, infra-red frequency signals in accordance with said communications protocols.

Salazar v. AT&T Mobility LLC, No. 2:20-cv-00004-JRG, 2020 WL 5608640, at *17 (E.D. Tex. Sep. 18, 2020) (emphasis altered) (citation omitted).

The district court held, and the Federal Circuit affirmed, that the term "a microprocessor" should be construed to mean "one or more microprocessors, at least one of which is configured to perform the generating, creating, retrieving, and

generating functions." *Id.* at 19; see also Salazar, 64 F.4th at 1317-18. In reaching its decision, the district court reasoned that the characteristics recited in the claims were "not just a simple listing of functions to be performed by 'a microprocessor" but "included[d] the functions that 'said microprocessor' [was] necessarily configured to perform as well as the structural relationship between 'said microprocessor' and other structural elements." *Salazar*, 2020 WL 5608640, at *19. The district court explained that "the repeated use of 'said microprocessor' to enumerate the functional and relational characteristics of 'a microprocessor' suggest[ed] that the same microprocessor that is 'coupled to' various structural elements is the one that is configured to perform the various recited microprocessor functions." *Id.* On appeal, the Federal Circuit agreed, noting that "while the claim term 'a microprocessor' [did] not require there be only one microprocessor, the subsequent limitations referring back to 'said microprocessor' require[d] that at least one microprocessor be capable of performing each of the claimed functions." *Salazar*, 64 F.4th at 1317.

The instant claims each introduce "an electrode" and subsequently dictate, in independent limitations, that "the electrode is configured to apply radiofrequency energy" and "the electrode is configured to apply pulsed electric current." 255 Patent at 30:51-31:2, 32:23-46. Unlike in *Salazar*, however, the operational relationship between "the electrode" and other structural elements does not logically require at least one electrode to be capable of delivering both energies. Consistent with the general rule of plurality, it suffices in this context to have "one or more electrodes . . . configured to apply radiofrequency energy" and "one or more electrodes

... configured to apply pulsed electric current." 4 Id. at 30:51-31:2, 32:23-46.

This result is supported by the '255 Patent's specification, which readily discloses that radiofrequency energy and electric current may be delivered by the same or separate electrodes. See, e.g., id. at 2:38-42 ("[I]t is necessary to improve medical devices providing more than one treatment energy (e.g. electromagnetic energy and electric current), such that both energies may be deliver[ed] via different active elements or the same active element (e.g. electrode)."), 19:51-53 ("The active element (e.g. electrode providing radiofrequency field and/or electric field) may be full-area electrode that has a full active surface."). Adopting Rejuva Fresh's narrower construction would improperly exclude disclosed embodiments. these See Broadcom Corp., 732 F.3d at 1333; Markman, 517 U.S. at 389.

The '255 Patent's prosecution history does not alter my analysis. Although Rejuva Fresh contends that the patentee's response to a Patent and Trademark Office Action—in which the patentee distinguished the invention from prior art on the basis that the prior art did not "teach or suggest an electrode configured to apply both radiofrequency energy and pulsed electric current"—supports their proposed construction, see ECF No. 149 at 7-8 (quoting ECF No. 149-1 at 11), nothing in the response reflects that, in order to obtain the '255 Patent, the patentee "unequivocally disavowed" construing the term "an electrode" to mean that the same or separate

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⁴ Contrary to Rejuva Fresh's argument, the use of the phrase "a second electrode" in Claim 21 is insufficient to demonstrate the patentee's clear intent to deviate from the general rule of plurality. See ECF No. 155 at 6-7; Baldwin, 512 F.3d at 1342. Claim 21's recitation of "a second flexible pad" comprising "a second electrode," wherein "the second electrode is configured to apply radiofrequency energy" and "the second electrode is configured to apply the pulsed electric current," Claim 21, Patent '255 at 32:65-33:20, is reasonably understood to mean the claimed device consists of at least two flexible pads, each of which has "one or more electrodes" configured to deliver one or both energies.

electrodes could deliver both energies, *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). As BTL notes, the general rule of plurality still applies and "the surrounding context of the statement shows the applicant used 'both' to mean that the prior art did not disclose pulsed electric current at all." ECF No. 148 at 8-9. Even if I were to conclude that the statement's meaning is ambiguous, which it is not, "[t]here is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term." *O1 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012) (quoting *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005)).

At bottom, nothing in the '255 Patent's claims, specification, or prosecution history demonstrates the patentee's clear intent to depart from the general rule that "an" means "one or more." *Baldwin*, 512 F.3d at 1342-43. I therefore conclude that a POSITA, after consulting that intrinsic evidence, would that understand the plain and ordinary meaning of the term "an electrode" is simply "one or more electrodes."

V. Conclusion

Based on the foregoing analysis, I recommend the Court define a POSITA as someone familiar with the design, development, and use of devices that apply radiofrequency energy and/or pulsed electrical energy to the body to stimulate biological tissue. This includes (1) a person with at least a bachelor's degree in electrical engineering, biomedical engineering, physics, or a related field of study, and at least two years of experience in academia or industry researching, designing, or

developing such devices, and (2) a medical doctor, healthcare professional, researcher, or other person with a degree in medicine, physiology, neuroscience, kinesiology, physical therapy, biomechanics, or a related discipline and two or more years of using, researching, designing, or developing such devices. I also recommend the Court construe the disputed terms as follows: the terms "enhance the visual appearance of the patient," as it appears in the '852 Patent, and "toned," as it appears in the '852, '386, and '575 Patents, are indefinite, see 35 U.S.C. § 112; the term "configured to," as it appears in the '852, '386, and '255 Patents, means "designed to"; the term "arranged on a circumference of," as it appears in the '519 Patent, means "arranged in close proximity with the circumference of"; and the term "an electrode," as it appears in the '255 Patent, means "one or more electrodes."

NOTICE

A party may file objections to those specified portions of a Magistrate Judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which <u>de novo</u> review by the District Court is sought, together with a supporting memorandum, within fourteen (14) days after being served with a copy thereof. A responsive memorandum shall be filed within fourteen (14) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to <u>de novo</u> review by the District Court and to appeal the District Court's order.

Dated: August 26, 2025

<u>/s/ Karen Frink Wolf</u>
United States Magistrate Judge